

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of propofol (4 mg/kg) and ketofol (2mg/kg propofol and 1mg/kg ketamine) for laryngeal mask airway insertion in children

Protocol summary

Summary

In this study we compare the effects of propofol and ketofol for LMA insertion in 60 children with ASA1 and 2 classes between 2-12 years old that candidate for surgery less than one hour. The patients are randomly divided in two groups : 30 patients in propofol group, receiving propofol 4 mg/kg and 30 patients in ketofol group, receiving propofol 2 mg/kg and ketamine 1 mg/kg. This study is a triple blind. Patients after entering operation room and preoxygenation with O2 100% for 2-3 minutes and standard monitoring (blood pressure, pulse oxymetry and ECG) are premedicate with midazolam 0.02 mg/kg and fentanyl 1 mcg/kg. Before and after anesthesia induction and after LMA insertion, vital signs (BP, HR, O2 saturation) are monitored. After injection of drugs, suitable LMA size are inserted (maximum effort for LMA insertion is 3 times). Time of loss of consciousness and eyelash reflex, severity of pain during injection, easiness and number of effort for LMA insertion, mouth opening for LMA insertion, swallow, cough, motion and laryngospasm are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502064041N10**

Registration date: **2015-04-07, 1394/01/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-07, 1394/01/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

TABRIZ UNIVERSITY OF MEDICAL SCIENCES

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propofol (4 mg/kg) and ketofol (2mg/kg propofol and 1mg/kg ketamine) for laryngeal mask airway insertion in children

Public title

Comparison of propofol (4 mg/kg) and ketofol (2mg/kg propofol and 1mg/kg ketamine) for laryngeal mask airway insertion in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 2-12 years old patients ; surgery less than one hour ; ASA 1 and 2 classes Exclusion criteria : risk of lung aspiration ; drugs allergy (propofol or ketamine) ; hard airway ; background neurological disease.

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for reaserch-Tabriz University of Medical Sciences

Street address

Tabriz-Golgasht Street-Medical University-Department of Vice Chancellor for reaserch

City

Tabriz

Postal code

Approval date

2014-04-28, 1393/02/08

Ethics committee reference number

9322

Health conditions studied

1

Description of health condition studied

anesthesia for surgery

ICD-10 code

K40.2

ICD-10 code description

K40.2 Bilateral inguinal hernia, without obstruction or gangren

Primary outcomes

1

Description

blood pressure

Timepoint

before and after anesthesia induction and after LMA insertion

Method of measurement

manometer

2

Description

heart rate

Timepoint

before and after anesthesia induction and after LMA insertion

Method of measurement

by device measurement

3

Description

oxygen saturation

Timepoint

before and after anesthesia induction and after LMA insertion

Method of measurement

pulse oxymeter

Secondary outcomes

1

Description

pain intensity during drug injection-ease of laryngeal mask airway insertion -number of try foraryngeal mask airway insertion

Timepoint

after induction

Method of measurement

scale

Intervention groups

1

Description

In operation room 30 patients in propofol group receiving propofol 4 mg/kg

Category

Treatment - Drugs

2

Description

In operation room 30 patients in ketofol group receiving 2 mg/kg propofol and 1 mg/kg ketamine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Seyed Hesam Fattahi

Street address

Tabriz - Sheshgilan Street - Children Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Golgasht Ave- Tabriz University of Medical Sciences

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty